K112047
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510(k) Summary

SEP 13 2011

Submission Date:	15 July 2011
Submitter:	Amcom Software, Inc. 10400 Yellow Circle Drive Eden Prairie, MN 55343
Submitter Contact:	Mr. Brian Edds Amcom Software, Inc. 10400 Yellow Circle Drive Eden Prairie, MN 55343 +1 (952) 230-5216 bedds@amcomsoft.com
Official Contact:	Mr. Thomas Kroenke Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 +1 (303) 956-4232 tkroenke@speedtomarket.net
Manufacturing Site:	Amcom Software, Inc. Commtech Division 8301 Cypress Plaza Drive, Suite 100 Jacksonville, FL 32256
Trade Name:	Amcom™ Commtech Messenger™
Common Name:	Network and Communication Middleware
Classification Name:	System, Network And Communication, Physiological Monitors
Classification Regulation:	21 CFR §870.2300
Product Code:	MSX

Substantially Equivalent Devices:

Amcom Software Model	*Predicate 510(k) Number*	*Predicate Manufacturer and Model*
Amcom Commtech Messenger	K102974	Philips Medical Systems / Intellisphere Event Management

Device Description: Amcom™ Commtech Messenger™ (Messenger) is an intelligent software medical device, also called middleware, which forwards critical information from medical devices to the user via display devices provided by Amcom or third-party device companies. It creates an enterprise-wide hub for the management, prioritization, and response to key events. This includes the ability to send messages to the right people based on filtering and rules set up in the hospital, including escalated communications whenever necessary.

The ability of medical devices such as patient monitors (including telemetry), infusion pumps, and ventilators to provide real-time notifications of a change in condition is invaluable. These systems check physiological conditions and are linked to the patient via hard wire or wireless telemetry, depending on the patient's mobility. Getting notifications to medical staff who can take fast action not only increases patient safety, but can also save lives. Messenger allows users to be aware of their patients' status and alarm conditions when they are away from the patient and the medical devices associated with that patient.

Intended Use: The intended use of the Amcom™ Commtech Messenger™ (Messenger) is to provide an interface with clinical systems to forward information associated to the particular event to the designated display device(s).

For medical, near real time alarms, Messenger is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. Messenger does not alter the behavior of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audio and/or vibrating mechanism upon receipt of the alert.

Messenger is intended for use as a secondary alarm. It does not replace the primary alarm function on the monitor.

Technology Comparison: Messenger employs the same or similar technological characteristics as the predicate device.

Performance Testing:

Software Testing Messenger was designed and developed according to a robust software development process, and was rigorously verified and validated.

Test results indicated that the Messenger complies with its predetermined specifications.

Electrical Safety Optional hardware available with Messenger was tested for electrical safety in accordance with applicable Standards.

Test results indicated that the Messenger complies with its predetermined specifications and with the applicable standards.

Electromagnetic Compatibility Testing	Optional hardware available with Messenger was tested for EMC in accordance with applicable Standards. Test results indicated that the Messenger complies with its predetermined specifications and with the applicable standards.
Performance Testing – Bench	Messenger was tested for performance in accordance with predetermined specifications. Test results indicated that Messenger complies with its predetermined specifications.
Conclusion	Verification and validation activities were conducted to establish the performance and safety characteristics of Messenger. The results of these activities demonstrate that Messenger is safe and effective when used in accordance with its intended use and labeling. Therefore, Messenger is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Amcom Software, Inc.
c/o Mr. Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
P.O. Box 3018
Nederland, CO 80466

SEP 13 2011

Re: K112047
Trade/Device Name: Amcom™ Commtech Messenger™
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: 74 MSX
Dated: July 15, 2011
Received: July 18, 2011

Dear Mr. Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112047

Indications for Use

510(k) Number (if known): K 112047

Device Name: Amcom™ Commtech Messenger™

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112047